

**ARIZONA DEPARTMENT OF HEALTH SERVICES  
OFFICE OF THE DIRECTOR  
OFFICE OF ADMINISTRATIVE COUNSEL AND RULES**

**SUBSTANTIVE POLICY STATEMENT  
# SP-001-OD-OACR**

**CLINICAL LABORATORY RELEASE OF PATIENT TEST RESULTS TO  
A HEALTH INFORMATION EXCHANGE ORGANIZATION**

*This substantive policy is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under Arizona Revised Statutes section 41-1033 for a review of the statement.*

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The purpose of this substantive policy statement is to notify the public of the Department's interpretation that a clinical laboratory may share a patient's clinical laboratory test results with a Health Information Exchange organization (HIE).

An HIE is a record locator service that facilitates electronic communication between a source of health information (such as a clinical laboratory) and a physician who has certified that the physician has a treatment relationship with the patient whose information is being sought. An HIE does not store any clinical laboratory test results.

A.R.S. § 36-461 exempts all CLIA certified laboratories from state regulation by Title 36, Chapter 4.1, Article 2. However, A.R.S. § 36-470 is still instructive for CLIA certified laboratories. CLIA regulations require an "authorized person" to order laboratory tests and direct test results to be released only to "authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test." 42 C.F.R. §493.1241 and 493.1291. An "authorized person" is "an individual *authorized under State law* to order tests or receive test results or both." 42 C.F.R. §493.2. Therefore, CLIA regulation points to state law to determine what parties may receive clinical laboratory test results.

A.R.S. § 36-470(A) permits any person licensed under Title 32, Chapters 7 (Podiatry), 8 (Chiropractic), 11, Article 2 (Dentistry), 13 (Medicine and Surgery), 14 (Naturopathic physicians), 17 (Osteopathic physicians), and 29 (Homeopathic physicians) to order tests to be completed at a clinical laboratory. Additionally, persons licensed to practice medicine or surgery in another state or a person authorized by law or department rules may order tests to be completed at a clinical laboratory. A.R.S. § 36-470(A). A.R.S. § 36-470(B) directs a clinical laboratory to report test results to the person who authorized the laboratory test. Arizona law is silent on any other disclosure of clinical laboratory test results.

However, federal law provides further direction as to clinical laboratory test disclosures. HIPAA permits clinical laboratories to report test results to a non-ordering physician in order to treat a patient. 45 C.F.R. §164.506. Both clinical laboratories and physicians are HIPAA covered entities permitted to share patient information for the purposes of treatment. Also, HIPAA permits disclosure of a patient's protected health information to an HIE if the HIE has the required business associate agreement.

As defined above, the HIE would not receive or store clinical laboratory results. The role of the HIE is to facilitate communication between the patient's health care provider and entities, such as clinical laboratories, that possess clinical laboratory test results. According to the Department's interpretation, A.R.S. § 36-470 neither permits nor prohibits a clinical lab from disclosing clinical laboratory test results to an HIE. Because there is no prohibition on such a disclosure in Arizona law, disclosure of a patient's

clinical laboratory test results to an HIE consistent with HIPAA does not conflict with state law. Therefore, the Department believes a clinical laboratory may share clinical laboratory test results with an HIE when done in compliance with HIPAA.

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